

EXHIBIT O

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Via Electronic Mail

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Re: *Indivior, Inc. and Aquestive Therapeutics, Inc. v. BioDelivery Sciences International, Inc.*, Civil Action No. 5:15-cv-00350-D (E.D.N.C.), and

Aquestive Therapeutics, Inc. v. BioDelivery Sciences International, Inc.
Civil Action No. 5:19-cv-00505-D (E.D.N.C.)

Dear Counsel:

We write regarding various deficiencies in BDSI's production, to date, of relevant records. BDSI's continued delay in producing documentation relevant to the issues in the two subject cases is prejudicing Plaintiffs' ability to move the cases forward.

For example, as you are aware, Local Patent Rule 303.4 in the Eastern District of North Carolina requires the party opposing claims of patent infringement to either produce or make available for inspection or copying "[s]ource code, specifications, schematics, flow charts, artwork, formulas, or other documentation sufficient to show the operation of **any aspects or elements of an Accused Instrumentality** identified by the patent claimant" at the same time as service of the preliminary invalidity contentions. The preliminary invalidity contentions were served on August 12, 2021 in both cases. Yet, just last week, BDSI produced documents that it admitted were "under the control of BioDelivery relating to work done by ARx for BioDelivery," but had not yet been produced. Relatedly, based on the lack of substantive production in response to most, if not all, of the Requests for Production thus far, Plaintiffs believe it is likely that BDSI is in the possession, custody, or control of a variety of other documents that should have been produced by now, but that have not.

Turning more specifically to the 55 Requests for Production that Plaintiffs have served in each case, BDSI's productions, thus far, are significantly incomplete, and most, if not all, of the objections to the requests are improper.

First, regarding the objections, BDSI has not stated "with specificity the grounds for objecting to the request, including the reasons." Fed. R. Civ. P. 34(2)(B). It is well-accepted that a "[m]ere recitation of the familiar litany that an interrogatory or a document production request is overly broad, burdensome, oppressive, and irrelevant does not suffice as a specific objection." *Mainstreet Collection v. Kirkland's, Inc.*, 270 F.R.D. 238, 240 (E.D.N.C. 2010).¹ By way of example, for 53 of its 55 RFP responses, BDSI asserts that the request is "vastly overbroad, unduly burdensome, and not proportional to the needs of this case," but not once does BDSI explain the reason or the basis for this position (or any other of its objections).

As another example, in response to RFP 5 relating to the manufacturing and testing of BELBUCA, one of BDSI's conclusory objections is that "documents and things reflecting 'the manufacture ... of BELBUCA'" have "no relevance to the claims and defenses in this matter." Not only does BDSI provide no reasoning for this position, but the idea that the documents and things reflecting the manufacturing of the BELBUCA product—that is, the accused instrumentality in 19-cv-505—are not relevant, in a patent infringement case involving claims directed to films manufactured using certain techniques and under certain parameters, is patently absurd. BDSI's objections are improper and should be withdrawn, and its responses should be supplemented in a manner consistent with the Federal Rules of Civil Procedure.

Regarding the records that BDSI has produced to date, it appears that BDSI has limited its productions to four categories:

- NDA documents maintained within a single source folder in each case;
 - 6,411 records from source folder "NDA207932" in 19-cv-505 (PROD_BDSI_BEL_001);
 - 2,498 records from source folder "NDA105637" in 15-cv-350 (BDSI-BUN_PROD001);

¹ See also *Hy-Ko Prods. Co. v. Hillman Group, Inc.*, No. 5:09-MC-32, 2009 WL 3258603, at *2 (E.D.N.C. Oct. 8, 2009) ("In the usual instance, objections to discovery which simply recite stock phrases are not colorable. Generally, the mere cry of burdensomeness or irrelevance without any statement in support of these objections is disfavored by the court."); *Mills v. E. Gulf Coal Preparation Co., LLC*, 259 F.R.D. 118, 132 (S.D.W. Va. 2009) (finding "boilerplate objections ... completely unacceptable").

- Publicly available references and alleged prior art (PROD_BDSI_BEL_002 & PROD_BDSI_BUN_002);²
- A sampling of batch records from third parties in the 19-cv-505 case (PROD_BDSI_BEL_004); and
- Manufacturing batch records maintained by third party, ARx LLC but under the control of BDSI (PROD_BDSI_BEL_005 & PROD_BDSI_BUN_004).³

However, Plaintiffs' RFPs are clearly not limited to NDA materials, records submitted to the FDA, public references being relied upon by BDSI, and batch records. At this stage, BDSI's response to each and every RFP is lacking completeness, as described in more detail below.

Except for the narrow categories of productions identified above, it does not appear that BDSI has produced a single internal record in response to the RFPs. For example, and putting aside documents within the NDA source folders, BDSI has not produced:

- any agreements, contracts or documents relating to interactions with third parties (*see, e.g.*, RFPs 15, 48, 49);
- any internal documents regarding the development of, and decision to develop, the BELBUCA and BUNAVAIL products (*see, e.g.*, RFPs 7, 10, 11, 13, 14, 15, 33, 48, 49);
- any internal BDSI documents regarding the manufacturing and quality control of the BELBUCA and BUNAVAIL products (*see, e.g.*, RFPs 5, 6, 7, 8, 9, 10, 11, 13, 14, 16, 17, 18, 46, 48, 49);⁴
- any documents regarding the commercial market for the BELBUCA and BUNAVAIL products (*see, e.g.*, RFPs 33, 34, 37, 38, 39, 40);

² PROD_BDSI_BEL_003 & PROD_BDSI_BUN_003 are each a production of a single document from the file history of U.S. Patent No. 7,897,080.

³ Metadata corresponding to the documents produced as part of BDSI-BUN_PROD004 and BDSI-BEL_PROD005 is limited to file name; there is no metadata for any of the other fields identified in the Stipulated Order Governing Electronic Discovery (D.I. 60 in 19-cv-00505). To the extent that other metadata exists but was not provided, BDSI should update these productions to be consistent with the standards set forth in the Stipulated Order.

⁴ BDSI has produced documents maintained by a third party, ARx, that appear to be related to the manufacturing, testing, and quality control of ARx's production of the BELBUCA and BUNAVAIL products. However, no documents maintained by BDSI have been produced in response to these RFPs, and as noted, BDSI has incorrectly asserted that such documents are not relevant to the case. *See, e.g.*, BDSI's Response to RFP 5.

- any organizational charts or other BDSI operational documents (*see, e.g.*, RFP 41);
- documents related to the NDAs that are not maintained in the source folders previously identified, including documents related to the decisions to file the NDAs (*see, e.g.*, RFPs 1, 2, 3, 8, 34, 35, 36); and
- documents supporting BDSI’s non-infringement and invalidity contentions that have not yet been produced (*see, e.g.*, RFPs 12, 21-32, 35, 36, 39, 44).⁵

Remarkably, for 14 of the 55 RFPs, BDSI’s response is limited to general objections followed by a statement that BDSI “is willing to meet and confer.” This is not a proper response and requires immediate supplementation and correction. BDSI’s obligation is to either produce copies of responsive information, or offer a specific objection that (1) explains the basis for the objection, and (2) identifies whether any responsive materials are being withheld on the basis of that objection.⁶ BDSI does not get to pick and choose which RFPs it responds to, and which it can ignore for more than six months.⁷ BDSI’s failure to comply with the Federal Rules of Civil Procedure is improperly delaying discovery and prejudicing Plaintiffs.

BDSI has provided that it allegedly “will produce” nonprivileged, relevant documents for 41 of the 55 RFPs. Yet, Plaintiffs do not believe that BDSI has fully complied with a single request to date. One example demonstrating just how lacking BDSI’s productions have been is that, despite public records and filings indicating that BDSI submitted an Investigational New Drug application for BEMA Buprenorphine,

⁵ The categories of documents and things in this listing, and the cited RFPs, are exemplary only and are not limiting on BDSI’s RFP responses and the deficiencies in those responses. To be clear, Plaintiffs believe that BDSI has failed to fully respond to each and every RFP at this time.

⁶ While BDSI proposed a mutual exchange of privilege logs at a later time (see November 5, 2020 correspondence from K. Freeman at 2), privilege is not the only objection BDSI asserts in the responses.

⁷ The first sets of RFPs were served in May and June, 2021. BDSI has failed to meet its obligation to supplement or correct its responses in a timely manner. For example, BDSI offers various objections based on there not being a protective order entered at the time of its responses. To the extent BDSI was withholding any documents based on that objection (which BDSI did not identify, so there is no way for Plaintiffs to know), that objection should be withdrawn, as a protective order has been entered in both cases. Similarly, BDSI’s response to RFP 12 is, in part, contingent on receiving Plaintiffs’ Initial Infringement Contentions. Since the time that BDSI provided its response to RFP 12 in 19-cv-505, infringement and invalidity contentions have been served; yet, BDSI has not updated its response.

buprenorphine buccal soluble film on December 15, 2005, BDSI has only produced six documents with metadata indicating that the document existed before June 2011; and not one of those documents is a BDSI document.⁸ As noted above, various RFPs are specifically directed towards internal documents regarding the development of, and decision to develop, what became the BELBUCA and BUNAVAIL products. *E.g.*, RFPs 7, 10, 11, 13, 14, 15, 33, 48, 49.

To the extent BDSI disagrees and believes it has fully responded to any of the RFPs, please identify the RFP and the Bates range for the produced documents that are allegedly fully responsive.

Plaintiffs recognize that the parties are working towards productions of email correspondences consistent with section 2.3 of the Stipulated Order Governing Electronic Discovery (D.E. 60). However, the fact that the parties are currently working on producing emails is no excuse for the delay in production of responsive, non-email records and materials that should have been produced well-before now.

Plaintiffs request that BDSI supplement, update, and/or correct BDSI's responses to all 55 RFPs in both cases, and produce the non-email records responsive thereto, on or before Wednesday, February 16, 2022. If Plaintiffs do not receive supplemental responses and corresponding productions by then, Plaintiffs will take the necessary steps to compel discovery in order to avoid any more delay by BDSI. Additionally, Plaintiffs do not believe that a meet and confer would be productive until BDSI complies with the Federal Rules of Civil Procedure by either producing responsive records or providing a reasoned explanation that Plaintiffs could then consider for any objection to the RFPs.

Sincerely,



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⁸ There are other public records, such as press releases, that indicate BDSI must have other responsive documents in its possession. *See, e.g.*, March 2, 2011 PRNewswire Release, available at <https://www.prnewswire.com/news-releases/biodelivery-sciences-confirms-505b2-pathway-for-bema-buprenorphinenaloxone-for-opioid-dependence-following-fda-meeting-117228518.html> (describing a pre-IND meeting with the FDA on the development program for BEMA Buprenorphine/Naloxone, BDSI's potential treatment for opioid dependence).